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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,140	11/21/2000	Brian Hawtin	2000-0702.OR	6011

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EXAMINER	
WELLS, LAUREN Q	

ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,140	HAWTIN, BRIAN	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2002 and 07 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9-13,15,17,20-23,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,9-13,15,17,20-23,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 3-5, 9-13, 15, 17, 20-23, 28 and 29 are pending. The Amendment filed May 7, 2002, cancelled claims 2, 6-8, 14, 16, 18-19, 24-27, and amended claims 1, 3-5, 9-10, 12-13, 15, 17, 20-23, 28, and 29.

The Declaration filed June 7, 2002, has been received.

Response to Applicant's Arguments/Amendment

Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

The Amendment filed May 7, 2002, is sufficient to overcome the objections to claims 4-13 and 17-28 in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 17, 20, 21, 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for atopic eczema, psoriasis, contact sensitivity, dermatitis, ulcers of Crohn's disease, pemphigus, Behcet's syndrome, urticaria, urticaria pigmentosa, pyoderma gangrenosum, chronic skin ulcers, burns, bee and wasp stings, dermal nodular fibrosis, morphoea, does not reasonably provide enablement for skin disease or condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

In the instant case, an incredible amount of experimentation would be needed to determine what compositions and dosages thereof comprising sodium cromoglycate or nedocromil sodium, alkoxylated cetyl alcohol, and amphoteric surfactant treat which skin diseases and conditions. While the specification does provide examples for the treatment of atopic dermatitis, the specification provides no further direction or guidance in regard to the make-up and amounts of the compositions that would treat other skin disorders or conditions. While the prior art teaches that is known to treat atopic eczema, psoriasis, contact sensitivity, dermatitis, ulcers of Crohn's disease, pemphigus, Behcet's syndrome, urticaria, urticaria pigmentosa, pyoderma gangrenosum, chronic skin ulcers, burns, bee and wasp stings, dermal nodular fibrosis, morphoea (see GB 2202145) with nedocromil, the prior art does not teach the instant compositions for use in the treatment of all skin diseases or conditions. Given, the large scope of these claims, it would be impossible for one of ordinary skill to make the instant composition and use the instant composition to treat every skin disease or condition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 17, 20-21 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claim 13 is vague and indefinite, as the scope of the claim in unclear. Does "consisting substantially of" imply the same limitations as "consisting essentially of"? The specification does not further define this phrase, and one of ordinary skill in the art would not be apprised of its meaning.

(ii) The terms "light" and "soft" in claim 13 (lines 5-6) are relative terms which render the claim indefinite. The terms "light" and "soft" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(iii) The phrase "A composition as in Claim 1 that is useful for treatment of a skin disease or condition" in claim 17 (lines 1-2) is vague and indefinite, as it is not clear what the term "useful" means. Does it treat the skin disease or condition, or does it treat something else?

(iv) The phrase "skin disease or condition" in claims 15 (line 1), 17 (line 2) is vague and indefinite, as it is not clear whether skin describes both "disease" and "condition" or if any condition is being claimed.

(v) Claim 20 is vague and indefinite, as the metes and bounds of this claim are not clearly defined. How would one of ordinary skill know what diseases or conditions are thought to be involved in the that which is described in claim 20? The specification does not define all these diseases or conditions thought to be involved, and one of ordinary skill in the art would not be apprised of them.

(vi) Claim 21 is rejected for the use of improper Markush groups. See MPEP 2173.05(h) for examples of proper conventional or alternative Markush-type language (e.g., ". . .selected from the group consisting of. . .and . . ."). Specifically, the phrase "atopic dermatitis or eczema" is not clear. Why are these diseases "ored" together, while the rest are separated by commas?

(vii) Claim 29 is vague and indefinite, as it is confusing. How is a composition "adapted for use in medicine"? What does this mean?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 10-11, 12, 15, 17, 20-21, 23, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Motoaki et al. (EP 0189861) in further view of Maurin (5,888,478).

Totten et al. teach compositions of nedocromil for dermatological use. Disclosed is an oil-in-water emulsion comprising 4% glyceryl monostearate, 4% cetostearyl alcohol, 10% liquid paraffin, 5% isopropyl myristate, 2% CREMOPHOR A6 (alkoxylated cetyl alcohol), 2% CREMOPHOR A 25 (alkoxylated cetyl alcohol), 67% water, and 4% sodium nedocromil. Further disclosed is an ointment comprising liquid paraffin, white soft paraffin, and an active ingredient. The oil phase may also include one or more emollients, such as isopropyl myristate. Oil-in-water and water-in-oil forms of the composition are disclosed. The composition is disclosed as finding use in the treatment of hypersensitivity reactions which involve

inflammation, such as atopic eczema, psoriasis, dermatitis, apthous ulcers, Behcet's syndrome, pemphigus, urticaria, urticaria pigmentosa, ulcers of Crohn's disease, pyoderma gangrenosum, and others. Totten et al. fail to teach sodium cromoglycate and amphoteric surfactants. See pg. 2, line 4-pg. 11, line 15. The reference lacks an amphoteric surfactant and a foam form.

Motoaki et al. teach a composition comprising ionic oil-soluble substances, amphoteric surfactant, and nonionic substances. Disodium cromoglycate and andrenocrotical hormones are disclosed as anionic water-soluble medicines. Amphoteric surfactants of the carboxylated imidazoline type are disclosed. Polyoxyethylene cetyl ether is disclosed as a nonionic substance.

Maurin teaches compositions for topical application. Sodium cocoylamidoethyl,N-ethoxycarboxymethylglycinate is disclosed as an amphoteric surfactant for use in the composition. See abstract; Col. 7, lines 1-10; Col. 8, line 55-Col. 12, line 33.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the carboxylated imidazoline amphoteric surfactants of Motoaki et al. to the composition of Totten et al. because a) Totten et al. and Motoaki et al. are both directed toward topical pharmaceutical compositions comprising nedocromil sodium; b) Motoaki et al. teach that the addition of the amphoteric surfactant to a pharmaceutical composition improves the percutaneous absorption of the medicinal active agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the carboxylated imidazoline amphoteric surfactants of the combined references as the sodium cocoylamidoethyl,N-ethoxycarboxymethylglycinate of Maurin because sodium cocoylamidoethyl,N-ethoxycarboxymethylglycinate is a carboxylated imidazoline amphoteric surfactant and because Maurin teaches it as safely applicable to the skin.

Claims 1, 9, 15, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Motoaki et al. in further view of Lezdey et al. (5,190,917).

Totten et al. is applied as discussed above. The reference lacks corticosteroids.

Motoaki et al. is applied as discussed above.

Lezdey et al. teach a method for treating psoriasis, wherein a composition comprising corticosteroid is topically applied. The composition is capable of inhibiting the degranulation of mast cells and/or binding with mast cell mediators. See abstract; Col. 2, line 50-Col. 4, line 33.

Totten et al. and Motoaki et al. are combined as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the corticosteroid of Lezdey et al. to the composition of the combined references because Lezdey et al. and the combined references are both directed toward compositions for the treatment of psoriasis and it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Motoaki et al. in further view of Timmins et al. (4,883,792) and Collin et al. (5,959,137).

Totten et al. are applied as discussed above. The reference lacks amphoteric surfactant, disodium edetate, triclosan and benzyl alcohol.

Motoaki et al. is applied as discussed above.

Timmins et al. teach steroid cream formulations. Oil-in-water emulsions are disclosed as preferred cosmetic forms. Benzyl alcohol and disodium edetate are disclosed for use together in

composition, wherein the benzyl alcohol is a preservative and the disodium edetate is a metal chelating agent/antioxidant. See Col. 2, line 15-Col. 4, line 43; Col. 5, line 43-Col. 6, line 35.

Collin et al. teach compositions for topical application. Triclosan is disclosed as a preservative for use in topical compositions for the skin. See abstract; Col. 4, lines 56-65.

Totten et al. and Motoaki et al. are combined as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the benzyl alcohol and disodium edetate of Timmins et al. and the triclosan of Collin et al. to the composition of the combined references because a) the combined references, Timmins et al., and Collin et al. are all directed to topical pharmaceutical compositions; b) Totten et al. teach that the water phase of their composition may include one or more bacteriocidal and/or fungicidal preservatives, and benzyl alcohol is disclosed by Timmins et al. as a preservative, and triclosan is disclosed by Collin et al. as a bactericidal preservative that can be combined with other preservatives.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 29-39 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant composition against atopic dermatitis. This is seen to be an expected result based on the cited prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
June 17, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200